

Remarks

After the forgoing amendments claims 1, 3-9 and 15-24 are pending. Claims 10-14 and 25-32 were previously cancelled. Claims 1 and 24 being the independent claims.

Claim Rejections

Section 102(b) Rejections

Claims 1-9, 15-19, 21 and 24 stand rejected under section 102(b) as being anticipated by U.S. Patent No. 5,616,142 ("Yuan"). Yuan teaches a plating system for bone fixation for mammalian bone structures having a vertebral bone plate with first plate segment ("receiving piece") having two side grooves and a central cavity capable of accepting a complementary second segment ("sliding piece."). While Yuan discloses several embodiments, only one makes an attempt to control the movement between the sliding plates segments (Figs. 4a-4d). One plate segment contains side "serrated groove tenons" while the other contains a complementally "toothed tenons". These features add resistance to motion and passively oppose movement caused by a compressive or distractive force along the long axis of the device.

Yuan patent does not disclose any mechanism to actively control the movement between the plate segments. This omission is understandable when the primary purpose of the Yuan device is considered. In Yuan (column 1, lines 34 to 38), the inventors claim that "It is therefore the primary objective of the present invention to provide a vertebral auxiliary fixation device having the effect of holding a foreign object which is implanted in a vertebra to be fixed or is implanted between vertebrae to be fixed." In short, the device is primarily intended to act as an implant retainer and not as a modulator or controller of vertebral motion.

Control of vertebral motion is a critical function of vertebral plating systems and Yuan lacks active control. A plate with two sliding segments advantageously allows use of a single plate over a

defined range of patient sizes. It also advantageously accommodates bony subsidence after device implantation. However, the sliding plate design of Yuan does not allow the device to hold the significant compressive load that surgeons routinely apply at the time of implantation. Vertebral compression at the time of implantation is necessary since the compressive force applied by the surgeon enhances bone healing and fusion formation. Further, the Yuan device does not limit and control the amount of bony subsidence. That is, after implantation, the amount of distance available for bony subsidence is equal to the remaining travel permitted between the two sliding segments. Since the same plate is used on various patients with differing vertebral heights, the distance available for subsidence after plate application will necessarily vary between patients. This feature is extremely undesirable since excessive subsidence may lead to compression and damage of the adjacent nerve elements and negate the very purpose of the surgical procedure. Worse still, excessive subsidence may produce new and profound post-operative neurologic deficits.

In summary, a vertebral plate of appropriate design must control vertebral motion. For this reason, an additional plate segment must be added to the sliding components to provide this feature. The present invention has termed this component the “coupling member” or “coupler” and this component is in addition to each of the two segments attached to each of the two vertebral bodies. The Yuan invention does not disclose any separate plate member or component that actively controls motion between each of the sliding and the receiving members that are attached to each of two vertebral bodies.

In rejecting 1-9, 15-19 21 and 24 based on the Yuan Patent, citation is made to item #3
“...(b) a coupler means (coupling segment) being securable to the first plate segment and the second

plate segment (piece 20'), the coupler means being selectively adjustable to define the movement (compression and subsidence) of the bone structures in the aligned relationship;.....". As disclosed in the Yuan patent, piece 20' is a central plate segment used to produce a plate capable of engaging the middle vertebral body within a three vertebral body (two motion segments) construct. This is unequivocally demonstrated by the presence of bore holes that are intended to accommodate fasteners and attach the segment onto bone. Piece 20' provides absolutely no active control or modulation of the movement between each of a sliding and receiving member. Indeed, the Yuan patent clearly labels this segment as a "compound receiving/sliding piece" (column 4, line 4) and no claim is made that piece 20' can actively control motion.

This application, discloses and claims the use of a coupling means to actively control and modulate movement between each of the sliding and receiving member that are attached to a single motion segments consisting of two vertebral bodies. The term "coupler" as used in the this application differs entirely in design, form, and function from that of piece 20' of the Yuan invention. The coupling means of the present application and piece 20' of Yuan are entirely separate entities and the term "coupler" is the only common feature between them.

102(e) Rejection

Claims 1-9, and 15-24 stand rejected under section 102(e) as being anticipated by PG-Pub 2002/0183755 to Michelson ("Michelson"). Michelson attempts to address the deficiencies of the Yuan device by adding a coupling member to modulate and control the movement between the receiving and sliding segments of the plate. This coupler has one end anchored within a bore hole of one plate segment and another end retained within a slotted cut-out of the second plate segment.

Within the defined range of the slot, the two plate segments slide freely. Since the coupler can resist plate separation, the Michelson device is capable of maintaining a compressive force. Further, the Michelson application discloses that a ratchet feature may be introduced to restrict motion between the two plate segments or the coupler can be used to immobilize the segments altogether. That application also discloses an internal compression feature but this is not relevant to the present application.

The coupling mechanism disclosed by Michelson allows the plate to hold the compressive load applied by the surgeon at the time of implantation and thereby addresses one of the shortcomings of the Yuan device. However, all embodiments of the Michelson invention use the travel permitted by a single slot to permit both the adjustment of plate length (performed at the time of plate implantation) and the accommodation of bony subsidence (occurs after plate implantation). Thus, the Michelson device, like Yuan's, does not independently limit or control the amount of bony subsidence. That is, after implantation, the amount of distance available for bony subsidence is equal to the remaining travel permitted between the two sliding segments. Since the same plate is used to accommodate various patients with differing vertebral heights, the distance available for subsidence after plate application will necessarily vary between patients. The surgeon can not be assured that every patient is permitted only a pre-determined amount of subsidence. Indeed, sizable length adjustment in one patient may leave insufficient travel to effectively accommodate post-implantation subsidence while use of the very same plate on a different patient with little length adjustment can permit excessive subsidence. This feature is extremely undesirable and potentially dangerous. With inadequate subsidence, there is a significant risk that the bone may not fuse and, with excessive subsidence, there is a sizable risk that the adjacent nerve elements may be

compressed and damaged. These shortcomings are an inherent consequence of an inadequate design and can not be overcome by simply varying the length of the slot.

This application discloses the use of coupling mechanisms that independently control the adjustment of plate length and accommodation of post-operative subsidence. In the first embodiment, a coupling means (segment 30) is added that contains two side-by-side slotted cut-outs. A screw or similar fastener has one end anchored within a bore hole of one sliding plate segment and the other end of the fastener is retained within one slotted cut-out of segment 30. A second fastener is similarly anchored within a bore hole of the second sliding plate segment and the other end of the fastener is retained within the second slotted cut-out of segment 30. In this way, the movement of one sliding segment relative to segment 30 is used to adjust the plate length while the movement of the second sliding plate segment relative to segment 30 is used to accommodate subsidence. In additional embodiments, a slotted cut-out is placed into each of the sliding segments and a coupling mechanism is used to select between the slots. That is, in one configuration, the coupler is attached to the first sliding plate segment and moves within the slotted cut-out of the second sliding plate segment. In this configuration, the slot of the second sliding plate segment determines the extent of length adjustment. After the plate is set to appropriate length, the coupler configuration is changed so that it is now anchored to the second sliding plate segment and moves within the slotted cut-out of the first sliding plate segment. In this second configuration, the slot of the first sliding plate segment is used to accommodate post-operative subsidence.

Using these coupler mechanisms, the present invention is capable of overcoming all of the short-comings of the Yuan and the Michelson designs. Unlike the Yuan invention, the present

invention allows the plate to hold a compressive load that is applied by the surgeon at the time of implantation. Further, unlike the Yuan and Michelson inventions, the present invention permits the independent adjustment of plate length and the accommodation of bony subsidence. Thus, the implanting surgeon can be assured that every patient is permitted only a pre-determined amount of subsidence regardless of the extent of intra-operative length adjustment.

In addition to the preceding, the present invention discloses various plate configurations that can be used to construct longer bone plates and fixate three or more vertebral bodies. The application also discloses and claims various additional features that collectively enhance device function and utility.

Conclusion

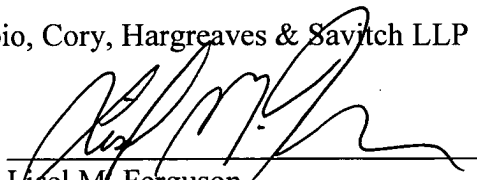
Applicant respectfully requests reconsideration and allowance of the above-identified application in view of the above amendments and remarks. If the Examiner has any questions or comments regarding the above amendments and remarks, the Examiner is respectfully urged to contact the undersigned at the number listed below.

Respectfully submitted,

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Dated: December 29, 2005

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